

Drug Approval Working Group (DAWG) & Aquatic Drug Approval Coalition (ADAC) Update



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*22nd Annual USFWS Aquaculture Drug
Approval Coordination Workshop*

June 10, 2016

So, what has happened since last year's meeting?

- Adjustments in DAWG members
 - ✓ Clint Peacock (Ga DNR)
 - ✓ NOAA has yet to find a replacement
 - ✓ Katie Haman accepted Co-chair
- DAWG Meeting, Annual AFWA Meeting
- DAWG/ADAC Meeting - Aquaculture 2016
 - ✓ Review of Tier I-III Drugs
 - ✓ Adjustments within the Tiers
 - ✓ A new drug survey
 - ✓ Offshore aquaculture
 - ✓ Develop ADAC Five Year Plan & Goals
 - ✓ VFD review team
 - ✓ AADAP Funding and INAD fees

DAWG Priority Drugs



Tier 1 - Highest Priority

- ✓ Drugs that have been identified by the DAWG as being of the highest priority based on the current needs of public aquaculture and fisheries management programs.
- ✓ Each drug has 1) an active and fully engaged drug sponsor; 2) an established Product Development Plan; 3) identified research and development funding; 4) a clear path, established timelines, and no identified impediments to ultimate FDA-approval.

Eugenol, and Emamectin

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Hydrogen peroxide, Chloramine-T, Eugenol, and Emamectin

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Chloramine-T, 17-MT, Eugenol, and Enamectin

DAWG Priority Drugs



Tier 2 - High Priority

- ✓ Drugs that have been identified by the DAWG as being of high priority based on the current needs of public aquaculture and fisheries management programs.
- ✓ Each drug has 1) an active and engaged drug sponsor; 2) an established Product Development Plan; 3) some level of anticipated research and development funding; and 4) no major, identified impediments to ultimate FDA-approval.

Oxytetracycline (oral & immersion), Copper Sulfate, Florfenicol, Hydrogen Peroxide, Chloramine-T and Formalin

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DAWG Priority Drugs

Tier 3

- ✓ Drugs that have previously been considered Tier 1 or Tier 2 drugs, but have been dropped (at least temporarily) to a lower classification as a result of an identified and significant impediment to approval. The priority of these drugs will be reconsidered bi-annually and potentially re-classified should the situation/impediment change.
- ✓ New drugs that been identified as both important to meet current and/or future aquaculture needs, and as potential suitable candidates for approval. The priority of these drugs will be reconsidered bi-annually and potentially re-classified.

Erythromycin & 17-MT



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Erythromycin

Ongoing Activities



Drug Survey

- ✓ Last survey of state agencies in 2006
 - Focused on the original drugs
- ✓ New survey will focus on fish health issues not met
- ✓ Presently in the planning phase

Offshore Aquaculture

- ✓ No approved drugs
- ✓ Need to engage NOAA
- ✓ Communicate the best path forward

Ongoing Activities

ADAC Five Year Plan and Goals

- ✓ Initial discussion and goals set at AFWA
- ✓ Plan and 9 Initial Goals developed in 11/2015
- ✓ 3 Top Priority Goals set at Aquaculture 2016
 - Fish Health Survey – focus on fish health issues not being met by present drugs
 - Review upcoming VFD change
 - Evaluate and initiate Congressional budget options to increase funding for aquatic drug approval activities by federal agencies
- ✓ Will provide a copy of plan and goals



Ongoing Activities

ADAC VFD Goal

- ✓ Team developed at Aquaculture 2016
- ✓ Chaired by Katie Haman

ADAC Congressional Funding

- ✓ Worked with drug sponsors, industry and states on Congressional letter to USFWS
- ✓ Reviewing other options for NOAA, USGS as well



Ongoing Activities

AADAP Funding and INAD Fees

- ✓ Base funding is still an issue
- ✓ Congress did increase funding slightly this FY
- ✓ MUMS Grants do help
- ✓ Need to consider lowered INAD fees for Tier I Priority Drugs
- ✓ Still a high priority to the AFWA and DAWG





Questions?

